



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,846	10/17/2003	Stephen E. Deal	(10000/210 PA-5357-RFB)	9428
757	7590	03/31/2006	EXAMINER	
BRINKS HOFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60610			TOY, ALEX B.	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/688,846	Applicant(s) DEAL ET AL.	
	Examiner Alex B. Toy	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
 4a) Of the above claim(s) 6, 8 and 9 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-26, 36-38 and 46 is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 10-17, 27-35 and 39-44 is/are rejected.
- 7) ☒ Claim(s) 45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's amendment filed on February 13, 2006. The objections to the title and drawings are withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Shockey et al. (U.S. Pat. No. 4,932,413).

Regarding claim 1, Shockey et al. disclose a catheter 10 comprising:

a shaft having a proximal end 14, a distal end 16, and a wire guide lumen extending through at least a portion thereof (Figs. 1 and 2a);

a plurality of intermediate wire guide access ports (20, 22, and 24) through a side wall of the shaft for providing access to the wire guide lumen, the intermediate wire guide access ports located between and spaced apart from the proximal 14 and distal 16 ends (col. 3, ln. 64-68 and Figs. 1 and 2a); and

at least one slidable tube 34 for allowing and restricting access to at least two of the plurality of the intermediate wire guide access ports (Figs. 2a and 2b).

Art Unit: 3739

Claims 1-5, 7, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Jang (U.S. Pat. No. 5,395,335).

Regarding claim 1, Jang discloses a catheter 10 comprising:

a shaft having a proximal end 14, a distal end 16, and a wire guide lumen extending through at least a portion thereof (Figs. 1 and 3);

a plurality of intermediate wire guide access ports (32, 34, and 54) through a side wall of the shaft for providing access to the wire guide lumen, the intermediate wire guide access ports located between and spaced apart from the proximal 14 and distal 16 ends (Fig. 1); and

at least one slidable tube 66 for selectively allowing and restricting access to at least two of the plurality of the intermediate wire guide access ports (col. 11, ln. 54-58 and Fig. 6).

Regarding claim 2, Jang discloses the catheter of claim 1, wherein the catheter is adapted for use with an endoscope having a working channel extending between a distal port and a proximal port. For the purposes of examination, "adapted for" is interpreted to mean "capable of." The catheter of Jang is capable of being used with an endoscope. Further, the plurality of intermediate wire guide access ports are accessible outside the endoscope when the catheter is positioned through the working channel such that the distal end of the catheter and the distal end of the working channel are substantially aligned. The endoscope is not positively recited or limited by the claim. Therefore, in the claimed position, the plurality of intermediate wire guide access ports

Art Unit: 3739

of Jang are accessible outside of any endoscope whose working channel is less than 80 cm long, since it can be at least 80 cm from the middle port 34 to the balloon 24 (col. 9, ln. 16-18 and Fig. 1).

Regarding claim 3, Jang discloses the catheter of claims 1 and 2 further comprising means for performing a medical procedure at the catheter distal end. Claim 3 invokes the means-plus-function language of 35 U.S.C 112, paragraph 6. Therefore, claim 3 is interpreted to include any "equivalent" structures for performing a medical procedure. See *In re Donaldson*. Jang discloses such an equivalent structure in using a balloon 24 at the distal end 16 for angioplasty (col. 8, ln. 44-45 and Fig. 1). In addition, at least one of the plurality of intermediate wire guide access ports is near the proximal port of the working channel of the endoscope when the catheter is positioned inside the working channel such that the means is positioned an optimal distance from the distal port of the working channel to perform the medical procedure. Again, it is possible to position the catheter of Jang as claimed since the terms "near" and "an optimal distance" have not been specifically defined.

Regarding claim 4, Jang discloses the catheter of claims 1-3, wherein the catheter includes a compression member 24 (Fig. 1). A compression member is interpreted to mean any structure, such as an angioplasty balloon, that is capable of applying pressure. Further, the compression member 24 has a portion extending external of the catheter 10, wherein means for performing a medical procedure comprises the portion of the compression member extending external of the catheter (Fig. 1). The inflated balloon extends external of the catheter shaft in an angioplasty

Art Unit: 3739

procedure. In addition, at least one of the plurality of intermediate wire guide access ports is near the proximal port of the endoscope working channel when the portion of the compression member extending external of the catheter is outside of and adjacent to the distal port of the endoscope working channel. Again, it is possible to position the catheter of Jang as claimed since the term “near” has not been specifically defined.

Regarding claim 5, Jang discloses the catheter of claims 1-4, wherein the means for performing a medical procedure comprises a sphincterotome 50 (Fig. 3). Applicant has not defined any specific structure in claiming a sphincterotome. Therefore, a sphincterotome is interpreted as any wire that could be used for cutting, and a wire 50 inserted into the lumen 20 could be used as such.

Regarding claim 7, Jang discloses the catheter of claims 1-3, wherein the means for performing a medical procedure comprises an irrigation catheter 22 (Fig. 6-). The catheter 10 includes a balloon inflation connector 26 in fluid communication with the lumen 22 and into the interior of the balloon 24 to inflate and deflate the balloon (col. 8, ln. 46-51 and Figs. 1 and 1B). Jang also discloses that the distal port 54 can be used as a perfusion opening (col. 11, ln. 49-52 and Fig. 1).

Regarding claim 13, Jang discloses the catheter of claim 1, wherein at least one of the plurality of intermediate wire guide access ports 32 is located approximately 50-56 cm from the proximal end 14 of the catheter shaft 10 (Fig. 1). Specifically, Jang details that access port 32 can be up to 60 cm from the proximal end 14, thereby satisfying the approximate distance of the claim (col. 8, ln. 65-67 and Fig. 1).

Claims 43 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Rowland et al. (U.S. Pat. No. 5,547,469).

Regarding claim 43, Rowland et al. disclose a method comprising the steps of :
advancing a sphincterotome having a proximal end 12, a distal end 14, and a plurality of intermediate wire guide access ports located a not insubstantial distance distal of the proximal end 12 and a not insubstantial distance proximal of the distal end 14 into an endoscope having a handle (col. 3, ln. 47-48); and

while a first intermediate wire guide access port 21 of the plurality of intermediate wire guide access ports is positioned near the handle of the endoscope, performing a sphincterotomy. The endoscope is not limited by the claim. Therefore, it is inherently possible for the first intermediate wire guide access port 21 of Rowland et al. to be near the handle of an endoscope in the claimed position.

Regarding claim 44, Rowland et al. disclose the method of claim 43, while the first intermediate wire guide access port 21 of the plurality of intermediate wire guide access ports is near the handle of an endoscope, further comprising the step of advancing a wire guide 57 through the first intermediate wire guide access port 21 (col. 6, ln. 17-18 and Fig. 5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3739

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jang in view of Sahatjian (U.S. Pat. No. 5,409,012).

Regarding claim 10, Jang discloses the catheter of claims 1-3 with a means for performing a medical procedure. The claim differs from Jang in calling for the means to be a tissue sampling device. Sahatjian, however, teaches a balloon angioplasty catheter with a tissue sampling device that uses suction to draw bodily sample material from the wall portion 14 through the openings 18 into the storage space 19 (arrows 26) (col. 3, ln. 60-64 and Figs. 3 and 3a). The tissue sampling device is used for diagnosing disease or monitoring progress of the treatment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made Jang's means for performing a medical procedure to be a tissue sampling device for diagnosing disease or monitoring progress of the treatment.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shockey et al. in view of Agro et al. (U.S. Pat. No. 6,152,910).

Regarding claim 11, Shockey et al. disclose a catheter in accordance with claim 1 comprising a plurality of intermediate wire guide access ports. The claim differs from Shockey et al. in calling for at least one marker adjacent to at least one of the plurality of intermediate wire guide access ports. Agro et al., however, teach a catheter with high contrast, color markers 48 for better visualization of the catheter during a procedure (col. 6, ln. 17-20 and Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Shockey et al. to have at least one marker adjacent to at least one of the plurality of intermediate wire guide access ports in view of Agro et al. for better visualization of the catheter during a procedure.

Claim 11 is also rejected under 35 U.S.C. 103(a) as being unpatentable over Jang in view of Agro et al.

Regarding claim 11, Jang discloses a catheter in accordance with claim 1 comprising a plurality of intermediate wire guide access ports. The claim differs from Jang in calling for at least one marker adjacent to at least one of the plurality of intermediate wire guide access ports. Agro et al., however, teach a catheter with high contrast, color markers 48 for better visualization of the catheter during a procedure

(col. 6, ln. 17-20 and Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Jang to have at least one marker adjacent to at least one of the plurality of intermediate wire guide access ports in view of Agro et al. for better visualization of the catheter during a procedure.

Claims 12 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jang.

Regarding claim 12, Jang discloses the catheter of claim 1 with a plurality of intermediate wire guide access ports 32, 34, and 54 (Fig. 1). Jang, however, does not expressly disclose that the plurality of intermediate wire guide access ports are at least about 150 cm from the distal end of the catheter shaft.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the plurality of intermediate wire guide access ports at least about 150 cm from the distal end of the catheter shaft because applicant has not disclosed that making the distance at least about 150 cm uniquely provides an advantage, is used in a particular purpose, or solves a stated problem that could not be achieved by a different distance based on the desired medical procedure and/or the size of the patient.

One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either the approximate distance shown in Jang's figures or the claimed approximately 150 cm because both distances can perform the

same function of making the plurality of intermediate wire guide access ports accessible on the proximal side of the proximal port of an endoscope working channel.

In addition, Jang discloses that the distance between the middle wire guide access port 34 and the balloon 24 can be up to 80 cm (col. 9, ln. 16-17 and Fig. 1). Taking into account the unspecified extra length of the balloon and distal tip, it is reasonable to assume that a plurality of intermediate wire guide access ports in the Jang catheter are close to about 150 cm from the distal end of the catheter shaft.

Therefore, it would have been an obvious matter of design choice to modify the catheter of Jang to obtain the invention as specified in claim 12.

Regarding claim 14, Jang discloses the catheter of claim 1, wherein one of the plurality of intermediate wire guide access ports 32 is located approximately 50-56 cm from the proximal end 14 of the catheter shaft 10 (Fig. 1). The claim differs from Jang in calling for two of the plurality of intermediate wire guide access ports to be located in a spaced apart fashion on the catheter shaft within approximately 50-56 cm from the proximal end of the catheter shaft. It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to make two intermediate wire guide access ports to be located in a spaced apart fashion on the catheter shaft within approximately 50-56 cm from the proximal end of the catheter shaft, since it has been held that mere duplication of the essential elements of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claim 15, Jang discloses the catheter of claim 1 with a plurality of intermediate wire guide access ports 32, 34, and 54 (Fig. 1). Jang, however, does not

Art Unit: 3739

expressly disclose that one of the plurality of intermediate wire guide access ports is located approximately 144-150 cm from the distal end of the catheter shaft.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make one of the intermediate wire guide access ports approximately 144-150 cm from the distal end of the catheter shaft because applicant has not disclosed that making the distance approximately 144-150 cm uniquely provides an advantage, is used in a particular purpose, or solves a stated problem that could not be achieved by a different distance based on the desired medical procedure and/or the size of the patient.

One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either the approximate distance shown in Jang's figures or the claimed approximately 144-150 cm because both distances can perform the same function of making the plurality of intermediate wire guide access ports accessible on the proximal side of the proximal port of an endoscope working channel.

In addition, Jang discloses that the guidewire removing means 40 can extend from the proximal wire guide access port 32 up to 10 cm or more proximal of the balloon 24; this length can be up to 100 cm (col. 9, ln. 63 – col. 10, ln. 15 and Fig. 1). Taking this 100 cm distance, plus the at least additional 10 cm distance to the balloon, and the unspecified extra length of the balloon and distal tip, it is reasonable to assume that the proximal wire guide access port 32 in the Jang catheter can be located approximately 144-150 cm from the distal end of the catheter shaft.

Therefore, it would have been an obvious matter of design choice to modify the catheter of Jang to obtain the invention as specified in claim 15.

Regarding claim 16, Jang discloses the catheter of claim 1, wherein (based on the preceding rejection of claim 15) it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the one proximal wire guide access port 32 located approximately 144-150 cm from the distal end of the catheter shaft.

The claim differs from Jang in calling for two of the plurality of intermediate wire guide access ports to be located in a spaced apart fashion on the catheter shaft approximately 144-150 cm from the distal end of the catheter shaft. It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to make two intermediate wire guide access ports to be located in a spaced apart fashion on the catheter shaft approximately 144-150 cm from the proximal end of the catheter shaft, since it has been held that mere duplication of the essential elements of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claim 17, Jang discloses the catheter of claim 1 with the shaft 10 further comprising a proximal half and a distal half, wherein two of the plurality of intermediate wire guide access ports 32 and 34 are in a spaced apart fashion on the catheter shaft 10 (Fig. 1). Jang, however, is silent on whether the two intermediate wire guide access ports 32 and 34 are each located on the proximal half of the catheter shaft 10 as claimed.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to locate each of the two intermediate wire guide access ports 32 and 34 on the proximal half of the catheter shaft 10 because applicant has not disclosed that locating each of two intermediate wire guide access ports on the proximal half of the catheter shaft uniquely provides an advantage, is used in a particular purpose, or solves a stated problem that could not be achieved by a different placement based on the desired medical procedure and/or the size of the patient.

One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either the approximate placement shown in Jang's figures or the claimed proximal half placement because both placements can perform the same function of making the plurality of intermediate wire guide access ports accessible on the proximal side of the proximal port of an endoscope working channel.

In addition, given the 30-60 cm distance from the proximal end 14 to the proximal access port 32 (col. 8, ln. 65-67), the 40-100 cm distance from the proximal access port 32 to the distal access port 54 (col. 9, ln. 63 – col. 10, ln. 15), and the additional unspecified distance from the distal access port 54 to the distal end 16, it is probably possible to make the two intermediate wire guide access ports 32 and 34 of Jang to be each located on the proximal half of the catheter shaft 10 as claimed. Minimizing the first distance from the proximal end 14 to the proximal access port 32 to be 30 cm, maximizing the distance from the proximal access port 32 to the distal access port 54 to be 100 cm, and taking into account the additional distance from the distal access port

Art Unit: 3739

54 to the distal end 16 would likely put the proximal access port 32 and the middle access port 34 on the proximal half of the catheter shaft.

Therefore, it would have been an obvious matter of design choice to modify the catheter of Jang to obtain the invention as specified in claim 17.

Claims 27, 29-35, and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jang in view of Pinchuk (U.S. Pat. No. 5,163,950).

Regarding claim 27, Jang discloses a catheter 10 having a shaft extending between a proximal end 14 and a distal end 16, a wire guide lumen 20 extending at least partially through the shaft, a plurality of intermediate wire guide access ports 32, 34, and 54 located between and spaced apart from the proximal end and the distal end, and a means 66 and 56 disposed on the catheter shaft for selectively allowing and restricting access to the wire guide lumen through at least two of the intermediate wire guide access ports (Figs. 3 and 6). The clause, "means ... for allowing and restricting access," invokes the means-plus-function language of 35 U.S.C 112, paragraph 6. Therefore, claim 27 is interpreted to include any "equivalent" structures for allowing and restricting access to the wire guide lumen through the intermediate wire guide access ports. See *In re Donaldson*. Jang discloses such equivalent structures in using a slidable cover 66 to cover or uncover the proximal port 32 (col. 11, ln. 54-56 and Fig. 6) and a removable, adhesive patch 56 to cover or uncover the distal port 54 (col. 11, ln. 22-24 and Fig. 5).

In addition, the plurality of intermediate wire guide access ports are accessible outside the endoscope when the catheter is positioned inside the endoscope working channel such that the distal end of the catheter and the distal port of the working channel are aligned. The size of the endoscope is not limited by the claim. Therefore, in the claimed position, the plurality of intermediate wire guide access ports of Jang are accessible outside of any endoscope whose working channel is less than 80 cm long, since it can be at least 80 cm from the middle port 34 to the balloon 24 (col. 9, ln. 16-18 and Fig. 1).

The claim differs from Jang in calling for a system comprising an endoscope having a working channel extending between a distal port and a proximal port. Pinchuk, however, teaches a balloon catheter 11 used with an endoscope 23 and 24 with a working channel extending between a distal port and a proximal port (col. 2, ln. 65 – col. 3, ln. 7 and Figs. 2 and 3). Pinchuk teaches a balloon catheter used with an endoscope for better direct visualization of the balloon compared to indirect visualization with fluoroscopy (col. 1, ln. 49-51). Further, Pinchuk's balloon catheter and endoscope kit can be designed for angioplasty (col. 3, ln. 15-16). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the balloon angioplasty catheter of Jang to have been used in a system with an endoscope in view of the teachings of Pinchuk for better direct visualization of the balloon compared to indirect visualization with fluoroscopy.

Regarding claim 29, Jang discloses the system of claim 27 in view of Pinchuk as stated in the preceding rejection of claim 27. In addition, Jang teaches the catheter

Art Unit: 3739

further comprising a proximal wire guide access port 64 for accessing the wire guide lumen 20 located a not insubstantial distance proximal of the intermediate wire guide access ports 32, 34, and 54 (col. 12, ln. 9-10 and Fig. 6) and a distal wire guide access port (at the distal end 16) for accessing the wire guide lumen 20 located a not insubstantial distance distal of the intermediate wire guide access ports 32, 34, and 54 (Fig. 5). Thus, claim 29 is unpatentable over Jang in view of Pinchuk.

Regarding claim 30, Jang discloses the system of claim 27 in view of Pinchuk as stated in the preceding rejection of claim 27. In addition, Jang teaches the catheter with a plurality of intermediate wire guide access ports 32, 34, and 54 (Fig. 1). Jang, however, does not expressly disclose that the plurality of intermediate wire guide access ports are at least about 150 cm from the distal end of the catheter shaft.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the plurality of intermediate wire guide access ports at least about 150 cm from the distal end of the catheter shaft because applicant has not disclosed that making the distance at least about 150 cm uniquely provides an advantage, is used in a particular purpose, or solves a stated problem that could not be achieved by a different distance based on the desired medical procedure and/or the size of the patient.

One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either the approximate distance shown in Jang's figures or the claimed approximately 150 cm because both distances can perform the

same function of making the plurality of intermediate wire guide access ports accessible on the proximal side of the proximal port of an endoscope working channel.

In addition, Jang discloses that the distance between the middle wire guide access port 34 and the balloon 24 can be up to 80 cm (col. 9, ln. 16-17 and Fig. 1). Taking into account the unspecified extra length of the balloon and distal tip, it is reasonable to assume that a plurality of intermediate wire guide access ports in the Jang catheter are close to about 150 cm from the distal end of the catheter shaft.

Therefore, it would have been an obvious matter of design choice to modify the catheter of Jang to obtain the invention as specified in claim 30.

Regarding claim 31, Jang discloses the system of claim 27, in view of Pinchuk as stated in the preceding rejection of claim 27. In addition, Jang teaches that at least one of the plurality of intermediate wire guide access ports 32 is located approximately 50-56 cm from the proximal end 14 of the catheter shaft 10 (Fig. 1). Specifically, Jang details that access port 32 can be up to 60 cm from the proximal end 14, thereby satisfying the approximate distance of the claim (col. 8, ln. 65-67 and Fig. 1).

Regarding claim 32, Jang discloses the system of claim 27 in view of Pinchuk as stated in the preceding rejection of claim 27. In addition, Jang teaches one of the plurality of intermediate wire guide access ports 32 is located approximately 50-56 cm from the proximal end 14 of the catheter shaft 10 (Fig. 1). The claim differs from Jang in calling for two of the plurality of intermediate wire guide access ports to be located in a spaced apart fashion on the catheter shaft within approximately 50-56 cm from the proximal end of the catheter shaft. It would have been obvious, however, to one having

Art Unit: 3739

ordinary skill in the art at the time the invention was made to make two intermediate wire guide access ports to be located in a spaced apart fashion on the catheter shaft within approximately 50-56 cm from the proximal end of the catheter shaft, since it has been held that mere duplication of the essential elements of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claim 33, Jang discloses the system of claim 27 in view of Pinchuk as stated in the preceding rejection of claim 27. In addition, Jang teaches a plurality of intermediate wire guide access ports 32, 34, and 54 (Fig. 1). Jang, however, does not expressly disclose that one of the plurality of intermediate wire guide access ports is located approximately 144-150 cm from the distal end of the catheter shaft.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make one of the intermediate wire guide access ports approximately 144-150 cm from the distal end of the catheter shaft because applicant has not disclosed that making the distance approximately 144-150 cm uniquely provides an advantage, is used in a particular purpose, or solves a stated problem that could not be achieved by a different distance based on the desired medical procedure and/or the size of the patient.

One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either the approximate distance shown in Jang's figures or the claimed approximately 144-150 cm because both distances can perform the same function of making the plurality of intermediate wire guide access ports accessible on the proximal side of the proximal port of an endoscope working channel.

In addition, Jang discloses that the guidewire removing means 40 can extend from the proximal wire guide access port 32 up to 10 cm or more proximal of the balloon 24; this length can be up to 100 cm (col. 9, ln. 63 – col. 10, ln. 15 and Fig. 1). Taking this 100 cm distance, plus the at least additional 10 cm distance to the balloon, and the unspecified extra length of the balloon and distal tip, it is reasonable to assume that the proximal wire guide access port 32 in the Jang catheter can be located approximately 144-150 cm from the distal end of the catheter shaft.

Therefore, it would have been an obvious matter of design choice to modify the catheter of Jang to obtain the invention as specified in claim 33.

Regarding claim 34, Jang discloses the system of claim 27 in view of Pinchuk as stated in the preceding rejection of claim 27. In addition, based on the preceding rejection of claim 33, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the one proximal wire guide access port 32 located approximately 144-150 cm from the distal end of the catheter shaft.

The claim differs from Jang in calling for two of the plurality of intermediate wire guide access ports to be located in a spaced apart fashion on the catheter shaft approximately 144-150 cm from the distal end of the catheter shaft. It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to make two intermediate wire guide access ports to be located in a spaced apart fashion on the catheter shaft approximately 144-150 cm from the proximal end of the catheter shaft, since it has been held that mere duplication of the essential elements of

a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claim 35, Jang discloses the system of claim 27 in view of Pinchuk as stated in the preceding rejection of claim 27. In addition, Jang teaches a catheter shaft 10 further comprising a proximal half and a distal half, wherein the at least two of the plurality of intermediate wire guide access ports 32 and 34 are in a spaced apart fashion on the catheter shaft 10 (Fig. 1). Jang, however, is silent on whether the two intermediate wire guide access ports 32 and 34 are each located on the proximal half of the catheter shaft 10 as claimed.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to locate each of the two intermediate wire guide access ports 32 and 34 on the proximal half of the catheter shaft 10 because applicant has not disclosed that locating each of two intermediate wire guide access ports on the proximal half of the catheter shaft uniquely provides an advantage, is used in a particular purpose, or solves a stated problem that could not be achieved by a different placement based on the desired medical procedure and/or the size of the patient.

One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either the approximate placement shown in Jang's figures or the claimed proximal half placement because both placements can perform the same function of making the plurality of intermediate wire guide access ports accessible on the proximal side of the proximal port of an endoscope working channel.

In addition, given the 30-60 cm distance from the proximal end 14 to the proximal access port 32 (col. 8, ln. 65-67), the 40-100 cm distance from the proximal access port 32 to the distal access port 54 (col. 9, ln. 63 – col. 10, ln. 15), and the additional unspecified distance from the distal access port 54 to the distal end 16, it is probably possible to make the two intermediate wire guide access ports 32 and 34 of Jang to be each located on the proximal half of the catheter shaft 10 as claimed. Minimizing the first distance from the proximal end 14 to the proximal access port 32 to be 30 cm, maximizing the distance from the proximal access port 32 to the distal access port 54 to be 100 cm, and taking into account the additional distance from the distal access port 54 to the distal end 16 would likely put the proximal access port 32 and the middle access port 34 on the proximal half of the catheter shaft.

Therefore, it would have been an obvious matter of design choice to modify the catheter of Jang to obtain the invention as specified in claim 35.

Regarding claim 39, the method claimed is inherent to using the catheter of Jang in view of Pinchuk. The catheter 10 of Jang having a proximal end 14, a distal end 16, a plurality of intermediate wire guide access ports 32, 34, and 54, and a means for performing a medical procedure 24 can be inserted into an endoscope having a working channel extending between a distal port and a proximal port (Fig. 1 of Jang and Fig. 3 of Pinchuk). Claim 39 again invokes the means-plus-function language of 35 U.S.C 112, paragraph 6. Therefore, claim 39 is interpreted to include any “equivalent” structures for performing a medical procedure. See *In re Donaldson*. Jang discloses such an

equivalent structure in using a balloon 24 at the distal end 16 for angioplasty (col. 8, ln. 44-45 and Fig. 1).

The catheter can be advanced through the working channel until the means for performing a medical procedure extends distally of the distal port of the endoscope working channel (Fig. 1 of Pinchuk). As stated in the preceding rejection of claim 3, it is concurrently possible to maintain a first intermediate wire guide access port of the plurality of intermediate wire guide access ports 32 proximal of and substantially adjacent to the proximal port of the working channel of the endoscope; and advance a wire guide 50 through the first intermediate wire guide access port 32 (Fig. 3 of Jang). In general, Pinchuk teaches that the catheter and endoscope combination can be made in a variety of sizes and shapes (col. 3, ln. 15-16), so the catheter and endoscope of Jang in view of Pinchuk is adaptable to anticipate size or positioning claims.

Regarding claim 40, the method of claim 39 is inherent to Jang in view of Pinchuk as stated in the preceding rejection of claim 39. In addition, Jang teaches a catheter including at least one slidable tube 66 for selectively allowing and restricting access to at least two of the plurality of intermediate wire guide access ports and a method comprising the step of opening a first slidable tube of the at least one slidable tube to allow access to the first intermediate wire guide access port 32 (col. 12, ln. 5-12 and Fig. 3).

Regarding claim 41, the method of claim 39 is inherent to Jang in view of Pinchuk as stated in the preceding rejection of claim 39. The catheter and endoscope of Jang in view of Pinchuk is further inherently capable of performing the method

comprising the step of, while performing the step advancing the catheter, maintaining the first intermediate wire guide access port proximal of and substantially adjacent to the proximal port of the endoscope working channel, positioning a second intermediate wire guide access port 34 of the plurality of intermediate wire guide access ports within the endoscope working channel.

Regarding claim 42, the method claimed is inherent to using the catheter of Jang in view of Pinchuk. Jang discloses a catheter having a proximal wire guide port 64 near a proximal end 14 of the catheter 10 (Fig. 6), a distal wire guide port near a distal end 16 of the catheter (Fig. 5), a plurality of intermediate wire guide access ports 32, 34, and 54 including a first 34 and second intermediate wire guide access ports (Fig. 5), at least one slidable tube 66 for selectively allowing and restricting access to each of the first and second intermediate wire guide access ports (Fig. 6), and a means 24 for performing a medical procedure (Fig. 5).

Claim 42 again invokes the means-plus-function language of 35 U.S.C 112, paragraph 6. Therefore, claim 42 is interpreted to include any "equivalent" structures for performing a medical procedure. See *In re Donaldson*. Jang discloses such an equivalent structure in using a balloon 24 at the distal end 16 for angioplasty (col. 8, ln. 44-45 and Fig. 1).

The catheter of Jang can then be inserted into an endoscope having a working channel extending between a distal port and a proximal port in view of Pinchuk as stated in the preceding rejection of claim 27. It is then inherently possible to advance the catheter through the working channel until the distal end of the catheter extends out

through the distal port of the endoscope working channel, wherein the first intermediate wire guide access port 34 is disposed within the endoscope working channel, and the second port is disposed proximally of and substantially adjacent to the proximal port of the working channel. It is further inherently possible to open one of the at least one slidable tube 66 to allow access to the second intermediate wire guide access port 32 and then insert a wire guide 50 through the second intermediate wire guide access port 32 (col. 12, ln. 5-12 and Fig. 3).

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jang in view of Pinchuk further in view of Agro et al.

Regarding claim 28, Jang discloses the system of claim 27 in view of Pinchuk as stated in the preceding rejection of claim 27. Claim 28 differs from Jang in view of Pinchuk in calling for the catheter to have at least one marker near at least one of the plurality of intermediate wire guide access ports. Agro et al., however, teach a catheter with high contrast, color markers 48 for better visualization of the catheter during a procedure (col. 6, ln. 17-20 and Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Jang in view of Pinchuk to have at least one marker near at least one of the plurality of intermediate wire guide access ports further in view of Agro et al. for better visualization of the catheter during a procedure.

Response to Arguments

Applicant's arguments filed February 13, 2006 have been fully considered but they are not persuasive.

Regarding claim 1, element 34 of Shockey is a slidable tube regardless of whether it is a part of the catheter or not. The structure of Shockey anticipates the structure as claimed. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the endoscope) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Further regarding claim 1, the slidable tube 66 of Jang is inherently capable of sliding along the catheter shaft 12 to selectively allow and restrict access to either access port 32 or access port 34 (Figs. 5 and 6).

Regarding claim 27, applicant claims only means for selectively allowing and restricting access to at least two ports. Jang discloses equivalent structures in using a slidable cover 66 to cover or uncover the proximal port 32 (col. 11, ln. 54-56 and Fig. 6) and a removable, adhesive patch 56 to cover or uncover the distal port 54 (col. 11, ln. 22-24 and Fig. 5). In addition, as with claim 1, the slidable tube 66 of Jang is inherently capable of sliding along the catheter shaft 12 to selectively allow and restrict access to either access port 32 or access port 34 (Figs. 5 and 6). With respect to the endoscope, Jang alone does not disclose an endoscope but does in combination with Pinchuk as

Art Unit: 3739

explained in the preceding rejection. Further, the size of the endoscope is not limited by the claim. Therefore, in the claimed position, the plurality of intermediate wire guide access ports of Jang are accessible outside of any endoscope whose working channel is less than 80 cm long, since it can be at least 80 cm from the middle port 34 to the balloon 24 (col. 9, ln. 16-18 and Fig. 1).

Regarding claim 39, the limitation "substantially adjacent to" is vague. As with claim 27, the size of the endoscope is not limited by the claim. Therefore, in the claimed position, a first intermediate wire guide access port of the plurality of intermediate wire guide access ports of Jang is proximal of and substantially adjacent to the proximal port of any endoscope whose working channel is less than 80 cm long, since it can be at least 80 cm from the middle port 34 to the balloon 24 (col. 9, ln. 16-18 and Fig. 1).

Regarding claim 40, the slidable tube 66 of Jang is inherently capable of sliding along the catheter shaft 12 to selectively allow and restrict access to either access port 32 or access port 34 (Figs. 5 and 6).

Regarding claims 41 and 42, the limitation "substantially adjacent to" is vague. As with claim 27, the size of the endoscope is not limited by the claim and the slidable tube 66 of Jang is inherently capable of sliding along the catheter shaft 12 to selectively allow and restrict access to either access port 32 or access port 34 (Figs. 5 and 6).

Regarding claims 43 and 44, Rowland is relevant because applicant has not positively recited inserting a wire into the claimed wire guide access ports. Claiming "wire guide access ports" only specifies an intended use for said ports. Therefore, the ports of Rowland are inherently capable of performing the intended use of carrying a

Art Unit: 3739

wire. In addition, the endoscope is not limited by the claim. Therefore, it is inherently possible for the first intermediate wire guide access port 21 of Rowland et al. to be near the handle of an endoscope in the claimed position.

Allowable Subject Matter

Claims 18-26, 36-38, and 46 are allowed.

Claim 45 is objected to as being dependent upon rejected base claim 43, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The examiner suggests applicant amend claims to include "a plurality of sleeves" as in claim 18, as this limitation is allowable over the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

Art Unit: 3739

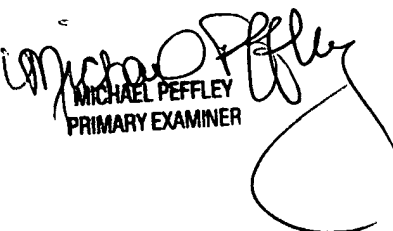
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT AT
3/24/06


MICHAEL PEFFLEY
PRIMARY EXAMINER